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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/814,001 03/30/2004		004	Edward J. Ellis	VIS-0008-P	6063		
23413	7590	4/18/2006		EXAMINER			
	COLBURN, LI		AUDET, MAURY A				
55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002				ART UNIT	PAPER NUMBER		
				1654	1654		
				DATE MAILED: 04/18/2006	6		

Please find below and/or attached an Office communication concerning this application or proceeding.

		1	Application No.	1	Applicant(s)				
Office Action Summary			10/814,001		ELLIS ET AL.				
		E	Examiner		Art Unit				
		1	Maury Audet		1654				
Ti Period for R	ne MAILING DATE of this communicately	ation appea	rs on the cover sheet w	vith the co	rrespondence ad	dress			
WHICHE - Extension after SIX ( - If NO peri Failure to Any reply	TENED STATUTORY PERIOD FOR VER IS LONGER, FROM THE MA soft ime may be available under the provisions of 6) MONTHS from the mailing date of this community of for reply is specified above, the maximum stature ply within the set or extended period for reply with received by the Office later than three months after them adjustment. See 37 CFR 1.704(b).	ILING DAT 37 CFR 1.136(a hication. tory period will a II, by statute, ca	E OF THIS COMMUNI a). In no event, however, may a apply and will expire SIX (6) MO use the application to become A	ICATION. reply be time NTHS from th BANDONED	ly filed e mailing date of this co (35 U.S.C. § 133).				
Status									
1)⊠ Re	sponsive to communication(s) filed	on <i>30 Mar</i>	ch 2004.						
· <u> </u>	This action is <b>FINAL</b> . 2b) This action is non-final.								
· · · · · ·	ce this application is in condition for	•—		tters, pros	ecution as to the	e merits is			
,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Disposition	of Claims								
4)⊠ Cla	im(s) 1-26 is/are pending in the ap	plication.							
, —	4a) Of the above claim(s) is/are withdrawn from consideration.								
	☐ Claim(s) is/are allowed.								
•	Claim(s) is/are cliewed.								
·	im(s) <u>1-26</u> are subject to restriction	and/or ele	ection requirement.						
Application	Papers								
	specification is objected to by the	Examiner							
,	•		ted or b)□ objected to	by the Ex	xaminer.				
•	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
	placement drawing sheet(s) including the				•	FR 1.121(d).			
	oath or declaration is objected to b			• • •		• •			
,	er 35 U.S.C. § 119	•							
- 12)□ Ack	nowledgment is made of a claim fo	r foreian nr	iority under 35 U.S.C.	& 119(a)-	(d) or (f)				
· · · ·	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:								
·	1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No								
3.[	_					Stage			
	application from the International	• •							
* See	the attached detailed Office action	•	, ,,	t received					
			·						
Attachment(s)									
1) Notice of	References Cited (PTO-892)		4) Interview						
	Draftsperson's Patent Drawing Review (PT0 on Disclosure Statement(s) (PTO-1449 or P		_	(s)/Mail Date Informal Pat	e tent Application (PT0	O-152)			
•	(s)/Mail Date	. 3/35/00)	6)  Other:		,,				

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142 applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-8, 10-14, and 19-26, are drawn to an ophthalmic preparation comprising a glycoprotein (e.g. dairy whey, sweet whey, purified whey), or a glycoprotein substantially free of: immunoglubulins; beta-lactoglobulin; beta-lactoglobulin; alpha-lactalbumin; and bovine serum albumin; or a therapeutic package thereof; classified in class 514, subclass 8.
- II. Claims 1 and 9, drawn to an ophthalmic preparation comprising a conjugate/complex of a glycoprotein (e.g. dairy whey, sweet whey, purified whey) and at least one component selected from the group consisting of a lipid, phospholipids, and lipoprotein; classified in class 530, subclass 359.
- III. Claims 15-18, drawn to a method of treating dry eye comprising a glycoprotein substantially free of: immunoglubulins; beta-lactoglobulin; beta-lactoglobulin; alphalactalbumin; and bovine serum albumin; or a therapeutic package thereof; classified in class 514, subclass 912.

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The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are independent and distinct, each from the other. Namely, Invention I is drawn to a single compound, namely a glycoprotein; whereas Invention II is drawn to a conjugated/complexed compound of a glycoprotein and a lipid, phospholipids, or lipoprotein. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group.

Inventions I-II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products, either a glycoprotein alone (e.g. dairy whey) or a glycoprotein conjugated/complexed to a lipid, phospholipids, or lipoprotein can be used in a materially different process of using that product, for instance methods of treating nutritional needs, such as food products, food additives, or nutritional supplements (see e.g. Applicant's own specification page 8, para. 29).

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the

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invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and the search required for each group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

## Species Election

This application contains claims directed to the following patentably distinct species:

- 1. A single specific glycoprotein (e.g. dairy whey, sweet whey, purified whey) or glycoprotein substantially free of: immunoglubulins; beta-lactoglobulin; alpha-lactalbumin; and bovine serum albumin (if Group I is elected as the Invention);
- 2. A single specific conjugate/complex of a glycoprotein (e.g. dairy whey, sweet whey, purified whey) and at least one component selected from the group consisting of a lipid, phospholipids, and lipoprotein (if Group II is elected as the Invention; note that a the exact structure of the conjugate/complex must be defined in the election, e.g. dairy whey conjugated to the lipid phosphatidyl choline); or
- 3. A single, specific glycoprotein substantially free of: immunoglubulins; beta-lactoglobulin; beta-lactoglobulin; alpha-lactalbumin; and bovine serum albumin (if Group II is elected as the Invention).

The species are independent or distinct because a search for any of the above species is not necessarily co-extensive particularly with regard to the literature search and a reference, which would anticipate any one of the above species, would not necessarily anticipate or even make obvious another species, absent evidence to the contrary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 15, 19, and 22 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MA, 04/15/2006

PATENT EXEMINER

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